

Reconsideration and withdrawal of the rejection of record is respectfully requested.

***Summary of Status of Amendments and Office Action***

Claims 1-7 are pending in the application with claims 1, 3 and 6 being independent.

Claims 1-7 are rejected under 35 U.S.C. § 112, first paragraph, as not enabled.

***Response to §112, First Paragraph Rejection***

Claims 1-7 are rejected under 35 U.S.C. § 112, first paragraph as nonenabled. The Office Action asserts that there is no teaching in the art or specification supporting the prevention of disease by proteins which bind to p75NTR. Further, the Office Action asserts that although a method may be useful in the treatment of a disease, clinical correlation with prevention of a disease does not necessarily follow. The Office Action also asserts that without working examples, it would be unpredictable and would require undue experimentation for one of skill in the art to practice the claimed invention.

It is respectfully submitted that this rejection is based on a misunderstanding of the present invention. Applicants note that the Office Action is based on the premise that Applicants are claiming compounds which would *per se* treat, prevent and/or diagnose a disease. However, the rejection does not apply because Applicants claims recite “an agent for use in screening a medicament for treatment, prevention and/or diagnosis of an apoptosis-associated disease which comprises an apoptosis related protein which binds to NADE (p75<sup>NTR</sup>- associated cell death executor) or a DNA encoding” the protein (claim 1, emphasis added). Thus, claim 1 recites an

agent for use in screening, not an agent to treat, prevent and/or diagnose a disease *per se*.

With respect to the statement in the Office Action regarding working examples, applicants note that working examples are in fact provided. However, Applicant respectfully points out that the inclusion of a number of representative examples is not required by the patent statute, and is not an end in itself. Rather, the examples are a means by which certain requirements of the statute may be satisfied. Thus, Applicant's inclusion of a number of representative examples in the instant specification is one way of demonstrating the operability of the broader invention, as well as teaching how to make and use the broader invention. However, Applicant should not be limited to the working examples, when the originally presented specification and claims establish the broader intent of the invention. Using the specification as a guide, including the examples on pages 10-18, a person of ordinary skill in the art would know how to use the invention to screen for molecules which bind to NADE and therefore are candidates for being agents which could treat, prevent and/or diagnose a disease. Therefore, Applicants respectfully submit that the basis for the rejection does not apply to the claimed invention and should be withdrawn.

Further, the rejection should be withdrawn because there would be no undue experimentation required to practice Applicants' disclosed and claimed invention in any bonded structure of optical material. *Ex parte Forman*, 230 U.S.P.Q. 546 (BPAI 1986); *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976); and *In re Herschler*, 200 U.S.P.Q. 711 (CCPA 1979).

As the Court of Appeals for the Federal Circuit stated in *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (CAFC 1988):

Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. "the key word is 'undue,' not 'experimentation.'

Wands states that the factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*, 230 U.S.P.Q. at 547. In particular, it is noted that these include (1) the quantity of experimentation, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Weighing these factors under the present circumstances clearly demonstrates that the 35 U.S.C. 112, first paragraph, enablement rejection is improper and should be withdrawn. In this regard, (a) the quantity of experimentation would be low, (b) there is sufficient direction presented, (c) working examples are provided, and (d) the relative skill in the art, the nature of the invention, and the claim language are sufficiently related that undue experimentation would not be required to practice the disclosed and claimed invention.

In view of the above, Applicants respectfully request that the rejection of claims 1-7 under 35 U.S.C. § 112, first paragraph be withdrawn.

## CONCLUSION

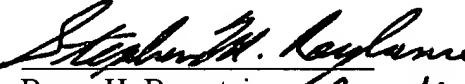
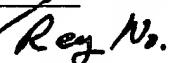
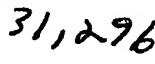
For the reasons advanced above, Applicants respectfully submit that all pending claims patentably define Applicants' invention. Allowance of the application with an early mailing date

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of the Notices of Allowance and Allowability is therefore respectfully requested. If any issues remain which may be expeditiously resolved by a telephone conference, the Examiner is respectfully invited to telephone the undersigned to discuss.

Should the Examiner have any further comments or questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
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